

Clexane[®] and Clexane[®] Forte^{*}

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Clexane?

Clexane contains the active ingredient enoxaparin sodium. Clexane is used to prevent clots from getting bigger or stopping new clots from forming following hospital procedures or illness. Clexane is also used to treat DVT and heart problems including unstable angina and heart attack when taken with aspirin. Clexane is used to stop blood clots forming in the tubes of your kidney dialysis machine.

For more information, see Section [1. Why am I using Clexane?](#) in the full CMI.

2. What should I know before I use Clexane?

Do not use if you have ever had an allergic reaction to Clexane, heparin or any medicine derived from heparin, or any of the ingredients listed at the end of the CMI. Do not take Clexane if you have or have had major bleeding disorders, injury to the brain, stomach or bowel problems, or bacterial infections of the heart.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Clexane?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Clexane and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Clexane?

- Your doctor will decide what dose you will receive.
- Clexane is usually administered by injection under the skin. It can also be injected into the tubing of a dialysis machine or into a vein by a doctor or nurse.

More instructions and how to use Clexane can be found in Section [4. How do I use Clexane?](#) in the full CMI.

5. What should I know while using Clexane?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using Clexane.• Tell your doctor if you become pregnant.• Tell your doctor if you have an artificial heart valve.• Tell your doctor you are using Clexane if you will be having a spinal or epidural injection for anaesthesia.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine without checking with your doctor.• Do not mix Clexane with other injections or fluids.• Do not inject Clexane into a muscle.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Do not freeze. Store in a cool dry place away from moisture, heat, or sunlight.• Keep the syringe in the pack until it is time to use it.

For more information, see Section [5. What should I know while using Clexane?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include pain, bruising, bleeding, swelling, itch, or rash at the injection site. Serious side effects include allergic reactions, signs of abnormal bleeding such as prolonged bleeding or bruising easily, nausea, gut pain, or numbness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Clexane® and Clexane® Forte*

Active ingredient: *enoxaparin sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Clexane. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Clexane.**

Where to find information in this leaflet:

1. [Why am I using Clexane?](#)
2. [What should I know before I use Clexane?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Clexane?](#)
5. [What should I know while using Clexane?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Clexane?

Clexane contains the active ingredient enoxaparin sodium. Clexane is an anticoagulant that belongs to a group of medicines called Low Molecular Weight Heparin (LMWH). These medicines help to prevent clots from getting bigger and stopping new clots from forming.

Clexane is used to prevent clotting following hospital procedures or illness. Clexane is also used to treat deep vein thrombosis and heart problems including unstable angina and heart attack when taken with aspirin. Clexane is used to stop blood clots forming in the tubes of your kidney dialysis machine.

2. What should I know before I use Clexane?

Warnings

Do not use Clexane if:

- you are allergic to enoxaparin sodium, heparin or any other medicines derived from heparin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have, or have ever had any of the following medical conditions:
 - o major bleeding disorders
 - o certain types of injury to the brain including stroke
 - o stomach or bowel problems, such as ulcers or ulcerative colitis
 - o bacterial infections in your heart

Check with your doctor if you:

- have or have had any of the following medical conditions:

- o major bleeding disorder or blood clotting problem including recent stroke or hereditary blood disorders
- o bacterial endocarditis, an inflammation of the lining of the heart caused by bacteria
- o an artificial heart valve particularly in women who are pregnant
- o uncontrolled high blood pressure
- o stomach or bowel problems such as ulcers or ulcerative colitis
- o kidney disease
- o liver disease
- o diabetes
- o eye disease related to diabetes
- o recent surgery on the brain, spine, or eye
- o spinal surgery or spinal deformity
- o underweight or overweight
- o high level of potassium in your blood

- take any medicines for any other condition

If your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection), tell your doctor you are using Clexane.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Clexane is not recommended while you are breastfeeding.

Children

- Do not give Clexane to a child.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Clexane and affect how it works such as:

- medicines used to prevent or treat blood clots, such as clopidogrel or ticlopidine
- medicines containing aspirin or salicylates
- Dextran 40, a medicine used to treat shock
- medicines used to treat inflammatory disease, such as non-steroidal inflammatory drugs, such as ibuprofen or diclofenac, or steroids such as prednisolone

- medicines which increase the level of potassium in the blood, such as potassium salts, fluid tablets and some medicines for heart problems

Your doctor will monitor your potassium levels and your ability to form blood clots if you are using any of these medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Clexane.

4. How do I use Clexane?

How much to use and when to use Clexane

- Follow the instructions provided and use Clexane until your doctor tells you to stop.
- Your doctor will decide what dose you will receive.
- Clexane is usually administered by injection under the skin.

For the prevention of blood clots

The usual dose for moderate risk patients is 20 mg once per day.

The usual dose for high risk patients is 40 mg once per day.

For the treatment of bloods clots in the leg or deep vein

The usual dose is 1 mg per kg of body weight twice per day or 1.5 mg per kg of body weight once per day.

Warfarin is usually started within 3 days of using Clexane.

For patients requiring dialysis

The usual dose is 1 mg per kg of body weight into the tubing of the dialysis machine at the start of the session. Additional doses may be needed.

For patients who have had severe heart attacks

- The usual dose is:
- 30 mg injected into the vein and 1 mg per kg of body weight injected under the skin, then
- 1 mg per kg of body weight twice per day.

For patients with other types of heart disease

The usual dose is 1 mg per kg of body weight twice per day. Your doctor may change this dose as needed.

How to use Clexane

- Clexane may be given by your doctor, nurse, or you.
- Clexane is usually given by injection under the skin or into the tubing of a dialysis machine. It can also be given by injection into a vein. This will be done in hospital by a doctor or nurse.

Prefilled syringes

The prefilled syringes are ready to use. The air bubble in syringe should not be expelled.

Graduated Prefilled Syringes

The graduated syringes have markings indicating the volume in the syringe. The volume (mL) or mass (mg) to be injected should be precisely measured according to the dosage recommended by your doctor.

Injection Technique

- The recommended site for injection is the stomach area. A different injection site should be used for each injection.
- The needle on the prefilled syringe is covered in a silicon coating. Do not wipe the needle or allow the solution to crystallise on the needle as this will damage the coating.
- Gently fold the skin using a thumb and finger. Hold the fold of the skin for the duration of the injection.
- Introduce the whole length of the needle vertically into the thickness of the skin fold and inject Clexane.
- Do not rub the injection site after administration.
- Clexane is for single use only. Use only once and discard after use.

If you use too much Clexane

If you think that you have used too much Clexane or have been given too much Clexane, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Clexane?

Things you should do

If you are about to be started on a new medicine tell your doctor, dentist, or pharmacist that you are using Clexane.

Tell your doctor immediately if you become pregnant.

Tell your doctor if you have an artificial heart valve.

If you plan to have surgery tell your doctor or dentist that you are using Clexane.

Tell your doctor that you are using Clexane if your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection).

Ask your doctor are there any activities, such as sports, you should avoid while using Clexane.

Tell your doctor if you experience any significant loss of weight or increase in weight.

Keep all your appointments with your doctor and any blood tests.

Remind any doctor, dentist or pharmacist you visit that you are using Clexane.

Clexane is not interchangeable with other medicines containing low molecular weight heparin medicines.

Things you should not do

- Do not give Clexane to anyone else even if they have the same condition as you.

- Do not use Clexane to treat any other complaints unless a doctor tells you to.
- Do not stop using Clexane or change the dosage without checking with your doctor.
- Do not mix Clexane with other injections or infusion fluids. Certain medicines or solutions contain ingredients that could interact with Clexane.
- Do not inject Clexane into a muscle.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Clexane affects you.

Looking after your medicine

- Store below 25°C
- Do not freeze Clexane
- Keep the syringes in the pack until it is time to use them

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection site-related <ul style="list-style-type: none"> • Pain, bruising or irritation • Hard, inflamed nodules • Itchy, red rash • Bleeding • Itchy skin 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergy-related	Call your doctor straight away, or go

Serious side effects	What to do
<ul style="list-style-type: none"> • Difficulty in breathing, symptoms of hayfever, feeling faint, itching hives, blisters, or other symptoms of allergy Injection site-related: <ul style="list-style-type: none"> • Painful itchy red/purple rash Bleeding-related: <ul style="list-style-type: none"> • Bleeding, including nose bleeds or prolonged bleeding from cuts • Bruising more easily than normal • Red or dark brown urine, red or black bowel motions • A fine widespread rash, especially noticeable on your mouth or eyes or sudden onset of white or blue colour in fingers in toes suggesting poor blood supply Spinal or epidural injection-related <ul style="list-style-type: none"> • Pain in the middle of your back • Numbness and weakness in your legs • Gut problems • Problems passing urine Other <ul style="list-style-type: none"> • Nausea, diarrhoea, fever • Swelling of the hands, ankles, or feet. • Severe abdominal pain, chest pain and headache • Numbness (paralysis), problems with coordination, dizziness, tiredness, light-headedness, • Blurred vision, confusion or difficulty speaking 	straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. These side effects are rare.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Clexane contains

Active ingredient (main ingredient)	enoxaparin sodium
Other ingredients (inactive ingredients)	water for injections
Potential allergens	enoxaparin sodium Contains materials of porcine (pig) origin

Do not take this medicine if you are allergic to any of these ingredients.

What Clexane looks like

Clexane is clear, colourless to pale yellow solution for injection.

It is available in the following syringes:

Ready to use Prefilled Syringes

- 20 mg of enoxaparin sodium per 0.2 mL (pack of 10)
- 40 mg of enoxaparin sodium per 0.4 mL (pack of 10)

Ready to use Prefilled Syringes with graduated markings

- 60 mg of enoxaparin sodium per 0.6 mL (pack of 10)
- 80 mg of enoxaparin sodium per 0.8 mL (pack of 10)
- 100 mg of enoxaparin sodium per 1.0 mL (pack of 10)
- 120 mg of enoxaparin sodium per 0.8 mL (pack of 10)
- 150 mg of enoxaparin sodium per 1.0 mL (pack of 10)

Who distributes Clexane

Distributed in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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Australian Registration Numbers

Pre-filled Syringes[#]

20 mg Aust R 42965

40 mg Aust R 42962

60 mg Aust R 56709

80 mg Aust R 56710

100 mg Aust R 56711

120 mg Aust R 74173

150 mg Aust R 74175

Prefilled syringes with safety lock system

20 mg Aust R 221717

40 mg Aust R 221718

60 mg Aust R 221719

80 mg Aust R 221720

100 mg Aust R 221721

120 mg Aust R 221722

150 mg Aust R 221723

Prefilled syringes with Eris safety lock system

20 mg Aust R 512346

40 mg Aust R 512345

60 mg Aust R 512347

80 mg Aust R 512348

100 mg Aust R 512349

120 mg Aust R 512350

150 mg Aust R 512351

Not marketed

* Subsequent references to Clexane refer to both Clexane and Clexane Forte.

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